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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

RAYMOND J. COLLETTE,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC.; SANDOZ INC.; and EON LABS, INC.,

Defendants.

CASE NO. 3:16-cv-01034-JD

DEFENDANTS SANDOZ INC. AND EON LABS, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS THIRD AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Fed. R. Civ. P. 12(b)(6)

Date: August 29, 2019
Time: 10:00 a.m.
Judge: Hon. James Donato
Courtroom: 11, 19th Floor

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

NOTICE OF MOTION AND MOTION TO DISMISS

PLEASE TAKE NOTICE that on August 29, 2019 at 10:00 a.m., or as soon thereafter as the matter may be heard before the Honorable Judge James Donato in the United States District Court for the Northern District of California, Courtroom 11, located on the 19th Floor of the United States Courthouse, at 450 Golden Gate Avenue, San Francisco, California, Defendants Sandoz Inc. and Eon Labs, Inc. will and hereby do move the court to dismiss the action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

Sandoz Inc. and Eon Labs, Inc. move to dismiss the Third Amended Complaint ("TAC") because the claims for relief asserted still fail to state any cause of action upon which relief may be granted. Plaintiff (1) continues to bring claims that have already been dismissed with prejudice by the Court and attempts to add new claims in direct violation of this Court's instructions; (2) brings claims that are all preempted by federal law; (3) alleges time-barred causes of action precluded by the statute of limitations; (4) has not fixed the inadequacies of pleading identified by this Court in its prior Orders and has not sufficiently pled his fraud-based claims with the particularity of pleading required by Fed. R. Civ. P. 9(b); and thus fails to state a claim upon which relief may be granted. This Motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the accompanying Declaration, the pleadings and papers filed herein, and the argument of counsel at the time of any hearing.

DATED: July 24, 2019

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By /s/ Sara K. Thompson

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MEMORANDUM OF POINTS & AUTHORITIES

Defendants Sandoz Inc. and Eon Labs, Inc. (collectively "Sandoz Defendants"), pursuant to Fed. R. Civ. P. 12(b)(6), 8(a)(2) and 9(b), submit this Memorandum of Points and Authorities in support of their Motion to Dismiss Plaintiff's Third Amended Complaint ("TAC"), stating as follows:

INTRODUCTION

Despite Plaintiff's attempts to amend the Complaint in compliance with the clear instructions contained in this Court's June 25, 2019 Order ("June 25, 2019 Order") (Dkt. 93), his amendment does not cure the many pleading defects identified by this Court, it directly violates the Court's explicit instructions, and his re-pled claims are still preempted, insufficiently pled, and barred by the statute of limitations. This purported product liability action asserts identical allegations against Defendant Wyeth Pharmaceuticals, Inc. ("Wyeth"), manufacturer of the prescription anti-arrhythmic drug Cordarone® and the Sandoz Defendants, manufacturers of generic amiodarone hydrochloride ("amiodarone"). Plaintiff Raymond Collette[1] ("Plaintiff") asserts in the TAC the same claims for failure to warn, off-label promotion, negligence, fraud and other California statutory claims as he pled in prior Complaints. (TAC ¶¶ 66-90). Additionally, Plaintiff's TAC asserts two new causes of action for failure to report adverse events and a manufacturing defect claim premised upon purported missing medication guides, despite the June 25, 2019 Order's explicit prohibition on adding new claims or defendants without leave of Court and explicit instructions that the Medication Guide claims were dismissed with prejudice and should not be re-pled. (TAC ¶¶ 59-65, 91-100). Plaintiff's claims in the TAC still center around alleged failure to provide "warning labels" and failure to provide a Medication Guide, which is an FDA-approved, patient-directed labeling document. (TAC ¶¶ 3, 14, 25). The Sandoz Defendants deny all such claims in their entirety.

Plaintiff filed his original Complaint (Dkt. 1) on March 1, 2016, a First Amended Complaint ("FAC") on August 26, 2016 (Dkt. 33), and a Second Amended Complaint on April 2, 2018 (Dkt. 78). The Sandoz Defendants and Wyeth filed Motions to Dismiss the SAC on April 16, 2018 (Dkt. 79). Oral argument was held on June 6, 2018. This Court issued the June 25, 2019 Order granting leave to amend

[1] While Plaintiff states in the TAC that a substitution of Jeanne Collette, Raymond Collette's surviving spouse, will be forthcoming, the TAC was not an effective substitution of Mrs. Collette as the Plaintiff in this action and no substitution has been filed as of the date of this Motion. In an effort to be consistent with the current status of pleading in this action, the Sandoz Defendants refer to Mr. Collette throughout as Plaintiff even though he passed away in June 2018 and the actions of Plaintiff's counsel in this action in the past year were likely undertaken on behalf of his surviving spouse and would-be substitute Plaintiff.

only the off-label promotion claims, while granting dismissal **with prejudice** of Plaintiff's claims regarding amiodarone's warnings and labeling and failure to provide medication guides. (Dkt. 93). The June 25, 2019 Order provided unambiguous instructions to Plaintiff on how to re-plead his remaining claims to comply with Fed. R. Civ. P. 9(b). *Id.* It also instructed Plaintiffs (1) not to re-plead the failure to provide Medication Guide claims, (2) not to attempt to add new claims or parties without express leave of court, and (3) to provide specific factual allegations sufficient to meet Rule 9(b) particularity requirements as to the off-label promotion claims as to each individual defendant. Plaintiff's TAC violates each of these 3 directives and could be stricken without further opportunity for relief on this basis alone.

The TAC should be dismissed because it pleads (1) causes of action beyond those allowed by the June 25, 2019 Order; (2) thinly veiled Medication Guide claims that are still preempted and do not contain "sufficient factual detail" to meet the plausibility requirements of Rule 8; and (3) off-label promotion claims that do not meet the particularity requirements of Rule 9(b). (Dkt. 93). In fact, the TAC does not include a single reference to a specific representation, promotional statement or promotional activity undertaken by the Sandoz Defendants, nor does it reference any such representation, promotional statement or activity made to any prescribing physician of Mr. Collette. Similarly, the newly added manufacturing defect claim is still directed to missing Medication Guide allegations that were dismissed with prejudice in the June 25, 2019 Order. (TAC ¶¶ 14, 96). These claims are still obviously "based purely on duties arising from federal regulations" (Dkt. 76), and Plaintiff's amended factual allegations do nothing to make them less dependent on the federal Medication Guides regulations at 21 C.F.R. §208.[2]

The Court also instructed Plaintiff that his off-label promotion claim "sounded in fraud" and must therefore "meet the heightened particularity standard under [Rule 9(b)]," and specifically "need[s] to say much more about what, specifically, each defendant said and did, and how those statements and actions (or lack thereof) relate to plaintiff personally and to his physician, Dr. James Yhip." (Dkt. 93 at 3-4). Yet, Plaintiff failed to make any substantive changes to the off- label promotion claims in the TAC to "tie [the claims] in any concrete way to himself 'and/or his prescribing physician.'" (*Id.* at 4). Instead, Plaintiff continues to vaguely plead that the Sandoz Defendants chose to benefit from prior promotion by other entities in developing and marketing a generic form of amiodarone, and adds new allegations of failure to

[2] Nor did Plaintiff add the pharmacy where he filled his prescriptions and from which he allegedly did not receive a Medication Guide, despite the Court's instructions to do so in this amendment in order to meet Rule 8 plausibility requirements. (Dkt. 76)

alert prescribing information publishers Epocrates and PDR.net that their information regarding amiodarone references off-label uses not approved by FDA. There are no specific allegations about promotional activities by the Sandoz Defendants directed to Plaintiff's prescribing physician Dr. Yhip, or any of the "who, what, when, and where" specifics required to comply with Rule 9(b). Plaintiff has done nothing in the TAC to make his fraud-based off-label promotion claim against the Sandoz Defendants meet the Rule 9(b) particularity standard, instead adding further vague allegations on irrelevant topics.

Finally, the TAC still contains claims that are time-barred on their face by the applicable statutes of limitations. While Plaintiffs add allegations about discovery of a Facebook page that they believe gives rise to a discovery rule argument, these allegations are easily disproven by the page itself, on which Jeanne Collette posted about her husband's injuries in 2012. Accordingly, each of Plaintiff's claims against the Sandoz Defendants should be dismissed, this time with prejudice and no further opportunity to amend. Additionally, the Sandoz Defendants request that this Court consider awarding fees and costs associated with this Motion as sanctions for Plaintiff's deliberate violation of the Court's orders in the TAC.

STATEMENT OF FACTS

I. REGULATORY BACKGROUND[3]

A. Regulatory History of Sandoz' Amiodarone.

Plaintiff asserts he was prescribed a 200mg course of amiodarone tablets manufactured by Sandoz, beginning in "January of 2012" for treatment of atrial fibrillation. (TAC ¶ 23.) Amiodarone is a prescription pharmaceutical product indicated for treatment of recurrent ventricular arrhythmias (recurrent ventricular fibrillation and recurrent hemodynamically unstable ventricular tachycardia) when other treatments are ineffective or have not been tolerated. Amiodarone was first manufactured and sold by Wyeth under the brand name Cordarone® in 1985. Eon Labs Manufacturing, Inc. (now known as Eon Labs, Inc. ("Eon")) obtained Abbreviated New Drug Application ("ANDA") approval for amiodarone 200 mg tablets on December 23, 1998.[4] Eon was required in ANDA #75315 to FDA to demonstrate bioequivalence to Cordarone® and to provide proposed labeling materially identical to the labeling for

[3] To avoid unnecessarily duplication, the Sandoz Defendants incorporate herein by reference section I.A., "The Regulatory Framework for Generic Drugs," pp. 4-5 of their Motion to Dismiss the Amended Complaint. (Dkt. 48.)

[4] Information on ANDA #75315 may be found on the FDA website, a true and correct copy of which is attached as **Exhibit A** to the Request for Judicial Notice ("RJN"), filed with the Sandoz Defendants' Motion to Dismiss the Second Amended Complaint. (Dkt. 80). A true and correct copy of the FDA approval letter for ANDA #75315 is attached as **Exhibit B** to the Request for Judicial Notice. (Dkt. 80) (*Id.*)

Cordarone®. *See* 21 U.S.C. §355(j)(2)(A). FDA reviewed and approved the proposed labeling, determining it was materially identical to that of the reference listed drug Cordarone®.[5] Eon was acquired by Sandoz in 2005 and transferred the ANDA approval to Sandoz. Federal law required Eon, and later Sandoz, to keep amiodarone's labeling -- including the Medication Guide -- and design the same as the approved labeling and design for Cordarone®. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575-77 (2011).

II. PLAINTIFF'S CLAIMS AGAINST THE SANDOZ DEFENDANTS

On July 10, 2019, Plaintiff filed the TAC, which is substantially similar to the SAC. Notably, the TAC still contains many allegations and claims that this Court ordered to be removed from the Amended Complaint because they were dismissed with prejudice. Specifically, Plaintiff continues to assert that he "did not receive the required Medication Guide in the form and manner required by law[.]" (TAC ¶ 14). Plaintiff's TAC also re-pleads failure-to-warn claims that were dismissed as preempted, including alleging "Defendants failed to disclose to the FDA, healthcare professionals, consumers, and Decedent the specific material adverse information they possessed concerning the number of incidents and actual adverse medical events, injuries, and deaths suffered by Amiodarone users." (Compare TAC ¶ 57 to SAC ¶ 76). Moreover, having already been ordered to drop "the claims going to the warnings and labeling for Amiodarone[,]" (Dkt. 76 at 2), Plaintiff nevertheless continues to assert labeling-based claims by attempting to incorrectly broaden the definition of "label" to include third party physician prescribing information applications.[6] (TAC ¶ 40). The June 25, 2019 Order explicitly prohibited Plaintiff from asserting claims regarding inadequate contents of warnings/labeling or failure to provide Medication Guides (Dkt. 93, at 2-3), yet the TAC continues to plead these meritless dismissed claims.

The TAC also repeats that the "Off-label prescription and distribution of Amiodarone for unapproved indications is a direct result of the long-term promotional efforts of Wyeth . . . as well as the Generic Defendants' pricing-based marketing scheme." (Compare TAC ¶ 50 to SAC ¶ 92.) Thus, the

[5] Sandoz' FDA-approved label is **Exhibit C** to the Request for Judicial Notice. (Dkt. 80).

[6] Plaintiff does not cite to any legal authority for this attempted expansion of the definition of labeling to include third party-published prescribing information applications, and in fact it is both legally and factually incorrect. It is also obvious that a manufacturer is not responsible for the content of publications that are entirely authored by third parties, so there is no basis to broadly interpret the statutes and regulations governing drug labeling to encompass these third party-published applications. Moreover, even if they could be so interpreted, these are entirely federal statutes and regulations that the Court has already ruled have no corollary in state law. Therefore, any claims premised upon such statutes and regulations are federally preempted.

TAC still impermissibly focuses on the purported conduct of entities other than the Sandoz Defendants as the basis for claims against the Sandoz Defendants.

Finally, in direct violation of the June 25, 2019 Order, Plaintiff alleges two new causes of action: purported failure to report adverse events, and a manufacturing defect claim that is really a disguised Medication Guide claim. (TAC ¶¶ 59-65, 91-100). The Court should dismiss these claims for blatantly ignoring the clear prohibition against adding new claims in the June 25, 2019 Order. (Dkt. 93 at 3-4).

Because the TAC is largely the same as the SAC, it continues to plead claims and theories of liability that many other federal courts have dismissed as preempted or insufficiently pled. *See, e.g.*, *Perdue v. Wyeth Pharm., Inc.*, No. 4:15-cv-208-FL, 2016 U.S. Dist. LEXIS 94636 (E.D.N.C. July 20, 2016)(dismissing all claims against generic manufacturers of amiodarone as preempted), *Elliott v. Sandoz, Inc.*, No. 2:16-CV-00861-RDP, 2016 WL 4398407, at *9 (N.D. Ala. Aug. 18, 2016)(dismissing failure-to-warn claims with prejudice as preempted); *McLeod v. Sandoz Inc.*, 4:16-cv- 01640-RBH, 2017 WL 1196801 (D.S.C. Mar. 31, 2017)(dismissing Medication Guide claims with prejudice as preempted); *McLeod v. Sandoz Inc.*, 2018 WL 1456739 (D.S.C. Mar. 23, 2018) (dismissing off-label promotion claims as preempted and insufficiently pled); *Tutwiler v. Sandoz Inc.*, No. 2:16-CV-01246-LSC, 2017 WL 3315381 (N.D. Ala. Aug. 3, 2017)(dismissing Medication Guide claims as preempted and off-label promotion claims as insufficiently pled and barred by the learned intermediary doctrine), *aff'd*, *Tutwiler v. Sandoz*, 2018 WL 1719024 (11th Cir. Apr. 9, 2018); *Bean v. Upsher-Smith Pharms., Inc.*, No.:4:16-cv-01696-RBH, 2017 WL 4348330, at *4-6 (D.S.C. Sept. 29, 2017)(same), *aff'd, Bean v. Upsher-Smith Pharms, Inc.*, No. 17-2263 (4th Cir. Apr. 8, 2019); *McDaniel v. Upsher-Smith Pharm., Inc.*, 893 F.3d 941, 944 (6th Cir. 2018) (medication guide-based claim is preempted because it "would not exist 'in the absence of the FDCA.'"). This Court should reach the same conclusion as these many other federal Circuit Courts of Appeal and District Courts, and dismiss these claims with prejudice.

ARGUMENT

I. PLAINTIFF VIOLATED THE DIRECTIVES IN THE JUNE 25, 2019 ORDER.

A. Plaintiff Continues to Plead Failure-to-Warn Claims Attacking the Labeling.

Plaintiff's first cause of action for failure-to-warn is not properly before the Court because it has already been dismissed in the Court's previous Orders. (Dkt. 93 at 2). Plaintiff's failure to warn claim is

based on Defendants' alleged failure to report adverse events to the FDA, which is demonstrably false, as Sandoz has already produced considerable documents to Plaintiffs demonstrating its reporting of adverse events associated with amiodarone to FDA. Regardless of its accuracy, the Court's June 25, 2019 Order stated, "The Court held in the prior order that 'the claims going to the warnings and labeling for Amiodarone, an FDA-approved generic drug, are preempted under federal law,' and 'must be removed from any amended complaint.'" *Id.* The Court also prohibited Plaintiff from adding new claims to the Third Amended Complaint, yet that is exactly what they did with their new failure to report adverse events claim, which was not asserted in prior complaints and was only noted in one passing reference in the SAC.

Despite having already been ordered twice to remove claims attacking the warnings and labeling for amiodarone, Plaintiff continues assert such claims in the TAC in flagrant disregard of the Court's directives. Plaintiff's attempt to refashion the failure to warn claims into failure to report adverse events claims also violates the instructions not to add new claims in this amendment. Due to these flagrant violations of the June 25, 2019 Order, the Court should again dismiss Plaintiff's failure-to-warn claims. The Sandoz Defendants further submit that because these violations of the Court's June 25, 2019 Order were clearly intentional, this Court should consider awarding fees and costs associated with the Sandoz Defendants' preparation of this portion of this Motion to Dismiss, as well as any oral argument on this point. If Plaintiff had followed the Court's instructions, these activities would not have been necessary.

B. Plaintiff Continues to Plead Failure-to-Distribute Medication Guide Claims, Which Are Preempted and Dismissed for the Reasons Previously Articulated by the Court.

Plaintiff's manufacturing defect claim is his latest attempt to assert the Medication Guide claims that the Court dismissed in its June 25, 2019 Order. (*Id.* at 3). The Order explained why the Medication Guide claims could not be pled with sufficient factual detail to meet the plausibility requirements of Rule 8 and were otherwise preempted. *Id.* Here, Plaintiff attempts to circumvent the Court's ruling by couching the previously-dismissed Medication Guide claims being based on the Sandoz Defendants' supposed failure to adequately label and package their products. This, of course, is an entirely new claim and cause of action that directly violates the Court's instructions not to add any new claims without express leave of Court. However, the manufacturing defect cause of action is also still specifically premised on the dismissed medication guide allegations as well, alleging "[t]he Manufacturer Defendants' fail[ed] to

ensure the Medication Guides were properly printed, affixed, distributed, and received[.]" (TAC ¶ 96). Because these claims were already dismissed with prejudice, were repackaged transparently under a new cause of action in violation of two different instructions in the Court's June 25, 2019 Order, and are still preempted by federal law because they are based entirely on federal regulations with no state law corollary, this claim should be dismissed with prejudice and with no further leave to amend. The Sandoz Defendants additionally assert that the Court may award fees and costs for this additional violation of the Court's June 25, 2019, which has further necessitated briefing that should have been unnecessary.

C. Plaintiff Adds New Causes of Action Despite the Court's Instructions Not to Do So.

The Court's June 25, 2019 Order ruled that "Plaintiff may not amend or re-allege his previously dismissed claims; nor may he add new claims or defendants without express leave of Court." (Dkt. 93 at 4). Despite this clear directive, Plaintiff both continues to re-allege his dismissed failure-to-warn and Medication Guide claims, and also attempts to add two new causes of action for failure to report adverse events and manufacturing defect. (TAC ¶¶ 59-65, 91-100). Plaintiff made the deliberate decision to ignore the Court's explicit instructions and intentionally violated the Court's Order. Not only is dismissal of these prohibited claims appropriate as punishment for these intentional violations, but the Sandoz Defendants request that the Court award fees and costs associated with moving to dismiss these prohibited claims.

D. Plaintiff's New Causes of Action Would Still Be Preempted and Inadequately Pled Even If They Were Appropriately Before the Court.

Despite this Court's ruling that all warning-based claims were dismissed with prejudice and should not be re-pled, the TAC largely restated these claims. The Court's prior March 12, 2018 Order made clear:

> "Several Supreme Court decisions have reviewed state laws for drug labeling, and they mandate the conclusion here that the claims going to the warnings and labeling for Amiodarone, an FDA-approved generic drug, are preempted under federal law…These types of allegations are preempted under *PLIVA*, are dismissed with prejudice for that reason, and **must be removed from any amended complaint**."

Dkt. 76, p. 2 (March 12, 2018) (emphasis supplied.). Not only are these same preempted attacks on the sufficiency, adequacy, clarity and accuracy of the warnings and labeling for amiodarone still throughout the TAC (along with preempted attacks on the safety and design of amiodarone), but Plaintiff has in fact added more attacks on the sufficiency of the warnings for amiodarone provided by the Sandoz Defendants. For example, TAC ¶¶59-65 adds new allegations that the Sandoz Defendants failed to disclose to the FDA

all adverse drug events related to Amiodarone use, which is ultimately a preempted failure to warn claim. This allegation also flies in the face of this Court's express ruling that "claims going to the warnings and labeling for Amiodarone, an FDA-approved generic drug, are preempted under federal law." (Dkt. 76.) Plaintiff's failure to warn claim necessarily contends Sandoz's labeling should have contained different or additional warnings, which *Mensing* unambiguously held to be preempted. 131 S. Ct. at 2577-81.

Plaintiff's new manufacturing defect claim is also simply a re-packaged Medication Guide claim and thus is also preempted, as this Court previously ruled. Plaintiff alleges "The Manufacturer Defendants either failed to follow appropriate written procedures regarding the labeling of Amiodarone or fail to have the required written procedures in place to ensure such labeling is both accurate and appropriately distributed." (TAC ¶ 94). In the SAC, Plaintiff states in his Medication Guide claim that "Defendants are simply not providing these warnings to patients." (SAC ¶ 87, 114). At its root, this new "manufacturing defect" claim is really a claim that the Sandoz Defendants failed to comply with federal Medication Guide regulations, which this Court properly recognized is a preempted claim. *See* Dkt. 93 at p. 3 (citing *McDaniel v. Upsher-Smith Labs*., 893 F.3d 941, 944-48 (6th Cir. 2018). As the Sixth Circuit has recognized and this Court has previously quoted, claims attempting to "enforce the federal regulation requiring drug manufacturers to ensure the availability of Medication Guides for distribution to patients," are impliedly preempted and as a result "the majority of district courts to consider this very issue have found identical claims preempted." *Id.* Thus, this repackaged medication guide claim is also preempted.

II. THE THIRD AMENDED COMPLAINT IS STILL INSUFFICIENTLY PLED.

Plaintiff's remaining off-label promotion claims are also subject to dismissal under Fed. R. Civ. P. 8(a)(2) and 9(b) because Plaintiff still fails to adequately plead all necessary elements of his claims as to the Sandoz Defendants. A complaint must contain a "plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 554 (2007). Dismissal is warranted if a complaint merely contains "naked assertions devoid of further factual enhancement," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. Plaintiff's TAC still contains only conclusory allegations and legal recitations devoid of any factual support as to the Sandoz Defendants, and thus should be dismissed.

A. Plaintiff's Fraud-Based Off-Label Promotion Claims Fail.

1. *Plaintiff Still Has Not Pled His Off-Label Promotion Claims with Particularity as to the Sandoz Defendants.*

As this Court's June 25, 2019 Order made clear, Plaintiff's off-label promotion claims are subject to the heightened particularity of pleading standard of Fed. R. Civ. P. 9(b), yet they still fail to meet this standard as to the Sandoz Defendants. Specifically, this Court ordered Plaintiff to include details in the TAC regarding "what, specifically, each defendant said and did and how those statements and actions (or lack thereof) relate to plaintiff personally, and to his physician Dr. James Yhip." (Dkt. 93 at 3-4). Despite those specific instructions, Plaintiff simply re-stated his original allegations that "Off-label prescription and distribution of Amiodarone for unapproved indications is a direct result of the long-term promotional efforts of Wyeth and the continuing sales efforts of Defendants through the PDR, Epocrates, and similar means, as well as the Generic Defendants' pricing based marketing scheme." (TAC ¶¶ 28, 50). Plaintiff still fails to attribute any specific promotional activities to the Sandoz Defendants with the requisite who, what, when and where, choosing instead to either make blanket allegations against all Defendants or focus on Wyeth's alleged conduct.[7] Plaintiff also still does not connect any specific promotional conduct at all of **any** Defendant to the decision by Dr. Yhip to prescribe amiodarone to Mr. Collette.

Thus, the TAC's fraud-based off-label promotion claims continue to fall woefully short of the pleading with particularity requirements of Fed. R. Civ. P. 9(b), as this Court made clear would be required to withstand a third Motion to Dismiss. Plaintiff should not be permitted to proceed with any of his fraud-based off-label promotion claims, since are still only pled in blanket, general fashion. California law requires that in actions for intentional fraud, a claimant is required to prove each and every element: "(a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or 'scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage." *Lazar v. Super. Ct.*, 12 Cal. 4th 631, 638 (1996). Further, every element of a fraud cause of action must be alleged both factually and specifically. *Cooper v. Equity General Ins.*, 219 Cal. App. 3d 1252, 1262

[7] Plaintiff's off-label promotion allegations are also contradicted by the widely recognized differences between marketing and promotional activities undertaken by brand manufacturers, who often employ sales representatives marketing their drug products directly to physicians, and generic manufacturers like Sandoz who generally do not employ sales representatives or market directly to physicians and instead market to and negotiate contracts with pharmacy and distributor customers on the basis of price and ability to provide consistent supply. Contrary to Plaintiff's allegations, Sandoz could not have promoted amiodarone to physicians for off-label uses, because Sandoz does not promote amiodarone to prescribing physicians at all.

(1990). When read together, Rules 9(b) and 12(b)(6) require a plaintiff to specifically allege each necessary element of a fraud claim as to each defendant in order to survive a motion to dismiss.

Plaintiff's vague blanket assertions in the TAC do not specify any purported off-label promotional conduct actually undertaken by the Sandoz Defendants. Plaintiff makes vague allegations about conferences allegedly sponsored by Defendants, articles allegedly funded by Defendants, and benefits derived by the Sandoz Defendants from the purported promotional activities of Wyeth prior to the Sandoz Defendants obtaining FDA approval for amiodarone. Yet, there is still not a single specific example in the TAC of off-label promotional activity undertaken by the Sandoz Defendants. The TAC does not identify or allege that the Sandoz Defendants sponsored any specific Continuing Medical Education conference to promote amiodarone for off-label use (because they have not done so), does not identify or allege that they funded any specific article promoting off-label use of amiodarone (because one does not exist), and does not contain a single example of a promotional statement by the Sandoz Defendants to Plaintiff's prescribing physician to before he prescribed amiodarone to Plaintiff. Thus, despite a detailed list of what a re-pled off-label promotion claim must include, Plaintiffs have provided none of the specifics required under Rule 9(b) in the TAC. This should be their last opportunity to do so, and dismissal should follow.

Plaintiff also does not identify the declarant, time, place or context of any purportedly fraudulent representations or omissions by the Sandoz Defendants. Plaintiff's fraud-based allegations are conclusory statements, unsupported by facts, and devoid of the requisite "particularity [of] the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Plaintiff's claims fail to state what, specifically, each defendant purportedly said and did, or how those statements and actions (or lack thereof) were received by and influenced the prescribing decisions of Plaintiff's physician. Federal courts in other cases involving amiodarone have dismissed nearly identical claims for failure to meet Rule 9(b) requirements.[8] Plaintiff fails to point to any specific promotional tatements made by the Sandoz Defendants to the prescribing

[8] *See*, *e.g.*, *Dreher v. Wyeth Pharm., Inc.*, No. 2:14-CV-00280, 2015 WL 3948961, at *6 (N.D. Ala. June 29, 2015) (dismissing off-label promotion claims for failure to "assert any *factual* allegations in support of his claims against the Generic Defendants for the off-label promotion of amiodarone."); *Elliott*, 2016 WL 4398407, at *8 ("[t]hese allegations do not satisfy the 'precise statements' or the 'time, place, and person' requirements of 9(b). Plaintiff fails to point to any statements made by Eon (or its agents) that misled Decedent, Decedent's physicians or any physician"); *Tutwiler*, 2017 WL 3315381, at *2 (dismissing off-label promotion claims where plaintiff failed to identify any promotional statements supporting plaintiff's allegations); *McLeod*, 2018 WL 1456739 (dismissing off-label promotion claims as preempted and insufficiently pled).

physician that could have induced him to prescribe amiodarone to Plaintiff, and thus Plaintiff's fraud-based claims must all fail for lack or particularity under Rule 9(b), without further leave to amend.

2. *Plaintiff Still Improperly Bases His Off-Label Promotion Claims on Third Party Conduct Rather than Conduct by the Sandoz Defendants.*

The TAC also continues to premise the off-label promotion claims on alleged conduct undertaken by brand manufacturer Wyeth, and then levies generalized, conclusory claims that the Sandoz Defendants willingly benefitted from Wyeth's prior alleged conduct, which the Sandoz Defendants deny. (TAC ¶ 42) ("The Generic Defendants, seeking to capitalize on and be the beneficiaries of the off-label marketing campaign initiated by Wyeth, received approval to manufacture, market, sell, and distribute the generic formulation of Amiodarone.") In the June 25, 2019 Order, the Court made clear this would be insufficient and directed Plaintiff "to 'say much more about what, specifically, each defendant said and did, and how those statements and actions (or lack thereof) relate to plaintiff personal and to his physician.'" (Dkt. 93 at 3-4). Plaintiff ignored those instructions, leaving the same allegations that the Sandoz Defendants benefitted from the promotional activities of other entities throughout the TAC without adding any further specific allegations about the Sandoz Defendants' conduct. Just as it was before, this "willing beneficiary" argument remains insufficient to properly plead an off-label promotion claim as to the Sandoz Defendants.

Substantively, Plaintiffs' off-label promotion claims must fail because Plaintiff cannot even plead, let alone prove, that any specific promotional statement by the Sandoz Defendants misled his prescribing physician to prescribe amiodarone to him. The California Supreme Court has held "the duty to warn runs *to the physician*, not to the patient." *Carlin v. Super. Ct. of Sutter Cnty.*, 13 Cal. 4th 1104, 1118 (Cal. 1996) (emphasis in original). In the case of prescription drugs, "if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to ensure that the warning reaches the doctor's patient for whom the drug is prescribed." *Id.* (citing *Stevens v. Parke, Davis & Co.*, 9 Cal.3d 51, 65 (1973)). California federal courts rely on the learned intermediary doctrine as well, finding a manufacturer discharges its duty to warn if it provides adequate warnings to the physician, regardless of whether the warning reaches the patient. *Motus v. Pfizer Inc.*, 196 F.Supp.2d 984, 990-91 (C.D. Cal. 2001); *see also Thomas v. Abbott Laboratories*, No. CV12-07005-MWF, 2014 WL 4197494 (C.D. Cal. 2014).

Thus, the relevant inquiry is entirely focused on what information the Sandoz Defendants allegedly did or did not provide to Dr. Yhip before he prescribed amiodarone to Plaintiff, but the Amended Complaint still lacks any such specific allegations. Because Plaintiff has not alleged Dr. Yhip would have changed his prescribing decisions had he received different or additional warnings about amiodarone, and has not alleged Dr. Yhip relied upon any representations or statements by the Sandoz Defendants specifically, Plaintiff's claims for alleged off-label promotion must fail as a matter of law.

B. Plaintiffs' Allegations Regarding Epocrates and PDR.net Do Not State a Plausible Claim and Should Be Dismissed.

The TAC continues to bring allegations regarding the Sandoz Defendants' purported interactions with or failure to correct the Epocrates and PDR.net physician prescribing information applications. Plaintiff erroneously characterizes the content on the Epocrates website as drug "labeling" as that term is defined by federal law: "[I]nformation about a particular drug in Epocrates or the PDR is considered 'labeling' under 21 U.S.C. § 321(m) and 21 C.F.R. § 202.1(1)(2) and state law, and as such is subject to a duty by Defendants to correct such information and cannot be false or misleading." (TAC ¶¶ 33-41, 87). Yet, the federal statute and regulation cited by Plaintiff here say no such thing. 21 U.S.C. §321(m) defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." This definition plainly does not include material on an electronic application published by a third party, because it is neither on the article itself or accompanying the article. 21 CFR §202.1(l)(2) does define certain writings "containing drug information supplied by the manufacturer, packer or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor" as "labeling" under federal law, but the information on both Eprocrates and PDR.net is compiled by their own in-house teams and is not distributed by or on behalf of the Sandoz Defendants. (*See* **Exhibits D and E** to RJN, from the Epocrates website and the PDR.net website, Dkt. 80). Thus, Plaintiff's assertion that these third-party created and published applications are part of the federally-regulated drug labeling is both plainly incorrect and legally unsupported.

Plaintiff also does not provide any legal support for his assertion that the Sandoz Defendants had any duty to communicate with non-FDA entities such as Epocrates or PDR.net to correct any references

to unapproved uses of amiodarone. It is not even clear as Plaintiff has pled this claim whether he believes Sandoz or Eon were aware of what these third party publishers said in their applications about amiodarone. Under *Twombly*, defendants are required to have "fair notice of what the claim is and the grounds upon which it rests[,]" but here Plaintiffs simply describe the Epocrates and PDR.net applications as "labeling", making a naked assertion devoid of any tie to required conduct by the Sandoz Defendants. *Twombly*, *supra*, 550 U.S. at 554.

In addition, publicly-available information on the Epocrates website directly disproves Plaintiff's allegations. The Epocrates website clearly states under "Content Sources" that "[t]he information about U.S. FDA-approved medications in Epocrates products is *proprietary content developed by the Epocrates Medical Information editors*." (*See* **Exhibit D** to RJN, from the Epocrates website, Dkt. 80) (emphasis added). The website goes on to explain that, at Epocrates:

> "This team of physicians and pharmacists continually and thoroughly researches and reviews information from the primary literature, specialty society recommendations, clinical guidelines, manufacturer labeling, standard medical references, and FDA drug safety alerts, *and then condenses that information into concise and clinically relevant monographs*. We believe this process produces the best available prescribing and drug reference information — *content that goes far beyond package inserts, with the inclusion of off-label and pediatric usage*."

In other words, Epocrates states it independently compiles information from several sources into the information provided in the application. The content on the Epocrates website and application that Plaintiff raises in the TAC is independent, proprietary content entirely separate from the labeling requirements the FDA imposes on pharmaceutical manufacturers. Epocrates expressly states its content "goes far beyond package inserts" and includes off-label usage information. Similarly, PDR.net's website states "the PDR Websites, the PDR Applications and the Services may also display other Content that does not reflect FDA-approved language and/or that is prepared by PDR or its Suppliers, such as: (i) summaries of side effects, warnings, precautions, indications and efficacy of drug products, and (ii) articles and other literature describing, among other things, research findings and news about drug products." (*See* **Exhibit E** to RJN, from the PDR.net website, Dkt. 80). In contrast, all labeling the Sandoz Defendants provide with amiodarone must be approved by the FDA at all times and may not include off-label use information. (*See* **Exhibit D** to RJN, Sandoz' amiodarone label, Dkt. 80). Accordingly, there is an obvious alternative explanation for how off-label information ended up in applications published by

Epocrates and PDR.net: the companies include in their applications information regarding dosage and other alternative uses for amiodarone that was not provided by the Sandoz Defendants or contained in the FDA-approved labeling, but rather was compiled by the companies themselves, as they state on their websites is their practice. Plaintiff's attempts to persuade this Court to presume that such information must have come from the Sandoz Defendants are factually and legally unsupported, and do not meet the clear instructions from this Court of the type of specific allegations as to each defendant that would permit this claim to survive this Motion to Dismiss.

At best, Plaintiff has pled a claim that the Sandoz Defendants knew or should have known that these websites and applications contained off-label use information and should have sought to correct it, but even then Plaintiff would be articulating a claim with no legal basis whatsoever in either federal or California law. Plaintiff's TAC provides no legal support for a purported duty to correct information published by third parties that was not provided by the manufacturer. Plaintiff has failed to state a plausible claim against the Sandoz Defendants with respect to these claims involving Epocrates and PDR.net.

III. PLAINTIFF'S OFF-LABEL PROMOTION CLAIMS ARE STILL PREEMPTED.

Claims premised entirely upon violations of exclusively federal duties arising under the FDCA and its regulations are impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001), in which the Supreme Court, citing 21 U.S.C. § 337(a), held "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with the [law]." Plaintiff's off-label promotion claims in the TAC allege the Sandoz Defendants violated FDA regulations making it "unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug," 21 U.S.C. §§ 331(d), 352(f), and 355. However, California law does not contain similar restrictions on off-label promotion and this claim therefore exists solely by virtue of the FDCA and its regulations.

As this Court noted in the March 12, 2018 Order, claims "based purely on duties arising from federal regulations" are preempted. (Dkt. 76 at 3). Thus, because off-label promotion claims are based solely on alleged violations of federal law, they are impliedly preempted under *Buckman*. *See Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1177 (C.D. Cal. 2013) ("any negligence claim based solely on

illegal off-label promotion is impliedly preempted under *Buckman* and § 337(a)").[9] Nothing in Plaintiff's TAC changes the preemption analysis.

IV. PLAINTIFF'S STATUTE OF LIMITATIONS ARGUMENT IS DEMONSTRABLY FALSE AND HIS CLAIMS ARE TIME-BARRED.

In a federal diversity action brought under state law, the state's statute of limitations applies. *Bancorp Leasing & Fin. Corp. v. Agusta Aviation Corp.*, 813 F.2d 272, 274 (9th Cir. 1987). Dismissal under Rule 12(b)(6) is appropriate when a plaintiff's complaint makes clear that his claims are barred by the applicable statute of limitations. *See Lukovsky v. City & Cnty. of S.F.*, 535 F.3d 1044, 1052 (9th Cir. 2008) (upholding dismissal on statute of limitations grounds); *M.O.R.E., LLC v. United States*, No. 12-cv-03609 (JST), 2015 WL 5093621, at *5 (N.D. Cal. Aug. 28, 2015); *Valasquez v. Mortgage Elec. Registration Sys., Inc.*, No. 3:08-cv- 03818 (PJH), 2008 WL 4938162, at *2-3 (N.D. Cal. Nov. 17, 2008).

The limitations "clock" begins to tick once the plaintiff "has notice or information of circumstances to put a reasonable person *on inquiry*…." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1110-11 (Cal. 1988), or when the cause of action accrues—i.e., when it "'is complete with all of its elements.'" *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 806-807 (2005) (quoting *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (1999)); *see also* Cal. Civ. Proc. Code §312. A cause of action accrues when, "under the substantive law, the [alleged] wrongful act is done," or the "wrongful result occurs, and the consequent liability arises." *Norgart*, 21 Cal. 4th, at 397. Thus, the limitations period starts to run "when a suit may be maintained." *Howard Jarvis Taxpayers Ass'n v. City of La Habra*, 25 Cal. 4th 809, 815 (2001) (quoting *Cnty. of San Diego v. Myers*, 147 Cal. App. 3d 417,421 (1983)). Plaintiff's causes of action have a two-year statute of limitations under Cal. Code Civ. Proc. §§ 335.1, 340.8(a). (SAC ¶¶ 116-146).[10] Yet, Plaintiff initiated this lawsuit over 3.5 years after his causes of action accrued.

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[9] In addition, numerous California district courts have held that off-label promotion claims are impliedly preempted under *Buckman*. *See*, *e.g.*, *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK, 2014 WL 3056026, at *5 (C.D. Cal. June 25, 2014) ("[T]here is no claim for illegal off-label promotion rooted in traditional state tort law. Therefore, any common law claim arising from such an action exists only by virtue of the FDCA. Permitting this claim to proceed would essentially allow a private litigant to attempt enforcement of the FDCA. *Buckman* bars such an action under § 337(a). Therefore, Plaintiffs' negligence claim based on off-label promotion is impliedly preempted."); *Anderson v. Medtronic, Inc.*, No. 14- CV-00615-BAS, 2015 WL 2115342, at *6 (S.D. Cal. May 6, 2015) ("There is no state law claim for negligence based on off-label promotion. In fact, there would be no such thing as off-label promotion without the federal statutory scheme. In other words, Plaintiffs allege Defendants are negligent because they violate the federal statutory scheme by promoting off-label use. Such a claim is impliedly preempted under *Buckman*.").

[10] *Viramontes v. Pfizer Inc.*, No. 2:15-cv-1754, 2015 WL 9319497, at *6-7 (E.D. Cal. Dec. 23, 2015) (negligence and products liability claims are subject to a two-year statute of limitations).

Plaintiff alleges he experienced the alleged side effects of amiodarone "[o]nly a few months" after being prescribed the drug in January 2012. (TAC ¶¶ 23-24). Thus, at that point he was on notice of a purported connection between his use of amiodarone and his side effects, and his cause of action accrued. However, Plaintiff did not file his initial Complaint until March 1, 2016, well after the two-year statutes of limitations had passed. These claims in the TAC are therefore time-barred.

The TAC argues the applicable statutes of limitations should be tolled "due to Defendants' conspiracy to conceal the true facts detailed herein through the use of deceptive and misleading forms of marketing and omissions of material fact from which either misled or prevented the FDA, the healthcare industry and public, including Decedent's physician, and Decedent." (TAC ¶ 27). As detailed throughout this Motion, Plaintiff's allegation is not supported by the facts. Moreover, Plaintiff's own admission in the TAC of how he came to learn that amiodarone was not an approved treatment for atrial fibrillation rests on his discovery of a "Stop Amiodarone" Facebook page on which his attorneys have posted, which he falsely alleges "was not published until early 2015." (TAC ¶ 25). However, the "Stop Amiodarone" Facebook page was created on August 18, 2010. (**Exhibit A** to the Declaration of Sara Thompson). In addition, a review of the publicly-available Facebook page reveals that Plaintiff's wife Jeanne Collette commented on the page in 2012 to inquire about her husband's alleged injuries that she believed were caused by amiodarone. (**Exhibit B** to the Declaration of Sara Thompson). Plaintiff's attempt to extend the applicable statute of limitations by falsely asserting he was unaware of the necessary elements of his cause of action until 2015 cannot withstand direct factual scrutiny, and thus his strict liability and negligence-based claims should be dismissed as time-barred.

CONCLUSION

This Court has given Plaintiff multiple opportunities to cure his defective pleading, but they should end now because Plaintiff clearly never intends to comply with this Court's instructions or to actually provide the requisite factual detail. Despite continual attempts to reshape and bolster these claims, Plaintiff cannot save claims that are fundamentally legally and factually lacking. Requiring the Sandoz Defendants to further brief and argue Motions to Dismiss claims that were intentionally pled in violation of Court Orders is unreasonable, and the Sandoz Defendants therefore respectfully request that this Court finally and definitively dismiss all such claims, with prejudice and without any further opportunities to amend.

The Sandoz Defendants also respectfully request that this Court consider whether these willful and intentional violations of the Court's Orders, by both repleading dismissed claims and adding new claims, have caused the Sandoz Defendants to unnecessarily need to brief and argue the instant Motion and whether fees and costs should be awarded as a result. The Sandoz Defendants may submit an accounting of attorney's fees and expenses at the Court's request.

DATED: July 24, 2019

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